(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 931 558 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
28.07.1999 Bulletin 1999/30

(51) Int Cl.[6]: **A61M 25/00**

(21) Application number: **99101045.5**

(22) Date of filing: **22.01.1999**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **23.01.1998 JP 2662198**

(71) Applicant: **Asahi Intecc Co., Ltd.**
Seto-shi, Aichi-ken (JP)

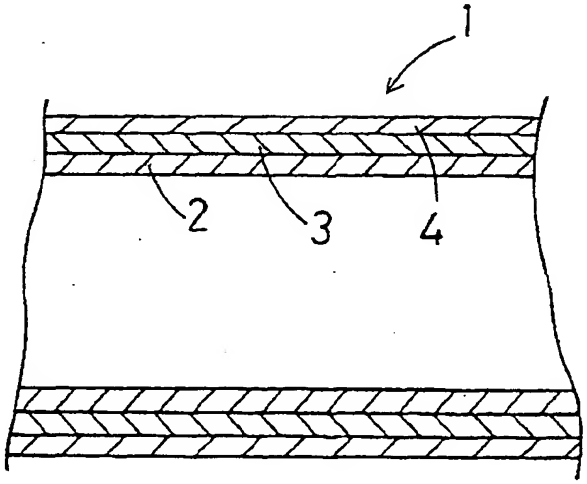
(72) Inventor: **The designation of the inventor has not yet been filed**

(74) Representative: **VOSSIUS & PARTNER**
Siebertstrasse 4
81675 München (DE)

(54) A catheter

(57) The object of the present invention is to present a catheter which can be safely inserted into the body and easily operated in said body. To attain this object, a catherter whose wall has a polylayer structure with more than three layers is provided in the present invention. In said catheter, the mechanical property changes gradually from inside layer to outside layer to obtain the minimum difference of the mechanical property between a pair of layers attaching to each other, so that high interlaminate strength is guaranteed and stress concentration is avoided. Further, in the case where the metal reinforcement is wound on the inner layer to obtain high rigidity, a catheter has a smooth surface without unevenness.

Fig. 1



EP 0 931 558 A2

Printed by Jouve, 75001 PARIS (FR)

Description

[0001] The present invention relates to a catheter used for diagnosis or therapeutics.

[0002] A catheter used for diagnosis or therapeutics is guided by guide wire from the outside of the body into the blood vessel, the trachea, the gonaduct, the ureter, etc. to reach a part to be treated to perform diagnosis or therapeutics. Accordingly, said catheter should be flexible enough to bend freely in the blood vessel etc. and not to injure the wall of the blood vessel etc. while said catheter should have a good torque transmission property and said catheter should be rigid enough for the good torque transmission property.

[0003] Hitherto, to solve said antinomy, catheters consisting of a base part having enough rigidity to transmit the torque and an end part having flexibility to bend freely have been presented (TOKKAISho 60-31765, Japanese Patent No. 2523405).

[0004] In TOKKAISho 60-31765, the tube wall of the catheter has a two-layer structure consisting of an inner tube part and an outer tube part and when the flexibility of said inner tube part is set to be smaller than the flexibility of said outer tube part, the thickeness of said inner tube part in said base part is set to be larger than the thickness of said inner tube part in said end part, and when the flexibility of said inner tube part is set to be larger than the flexibility of said outer tube part, the thickness of said outer tube part in said base part is set to be larger than the thickness of said outer tube part in said end part to give said base part high regidity for a good torque transmission property and said end part high flexibility to bend freely.

[0005] Further, in Japanese Patent No. 2523405, a catheter having a rigid base part and a flexible end part is provided wherein the glass transition temperature of the organic material of said base part is set to be higher than the glass transition temperature of the organic material of said flexible end part and further, a metal reinforcement is wound on the outside of said base part and still further, a synthetic resin coating is applied on said reinforcement to give said base part high rigidity.

[0006] Said catheter of TOKKAISho 60-31765 has faults in that the flexibility of said inner tube part is much different from the flexibility of said outer tube part, resulting in poor interlaminate strength between said inner tube part and said outer tube part and said catheter is easily folded by stress concentration.

[0007] Further, said catheter of Japanese Patent No. 2523405 has a fault in that the unevenness of the metal reinforcement appears on the surface of synthetic resin coating.

[0008] Accordingly, an object of the present invention is to present a catheter consisting of a base part having enough rigidity for a good torque transmission property and an end part having enough flexibity to bend freely.

[0009] To attain this object, a catheter whose tube wall has a polylayer structure with more than three layers is presented in the present invention.

[0010] In the present invention, said catheter consists of a base part and an end part, and said base part is reinforced by a metal reinforcement arranged on the outside of the inner layer to give said base part enough rigidity.

[0011] It is preferable that the glass transition temperature of said polylayer becomes gradually higher from the inside to the outside and the glass temperature of the outer layer is equal to or lower than the bodily temperature.

[0012] Further, it is preferable that said catheter has a three layer structure consisting of an inner layer, a middle layer, and an outer layer and said metal reinforcement arranged on the outside of the inner layer is covered with said middle layer and said middle layer and outer layer consist of the same material.

[0013] Still further, it is preferable that the material of said outer layer is in the rubbery state at the bodily temperature when said catheter is inserted into the body, the bending modulus of elasticity of said material is more than 1000 kgf/cm^2 at a temperature close to the bodily temperature, the material of said inner layer keeps the glassy state at the bodily temperature when said catheter is inserted into the body, and the bending modulus of elasticity of said material is more than 2500 kgf/cm^2 at 23°C.

[0014] Still further, it is preferable that 15000 kgf/cm^2 $\geqq G_1 \geqq$ 8000 kgf/cm^2 and 3500 kgf/cm^2 $\geqq G^3 \geqq$ 1000 kgf/cm^2 wherein G_1 is the bending modulus of elasticity of said inner layer and G_3 is the bending modulus of elasticity of said outer layer.

[0015] Still further, it is preferable that said catheter consists of a base part and an end part, and the thickness of the inner layer of said base part is larger than the thickness of the inner layer of said end part.

[0016] The invention will be described with reference to preferred embodiments and the drawings, in which:

[0017] Figure 1 to Figure 3 show an embodiment of the present invention.

[0018] Figure 1 is the enlarged partial cross sectional view of a catheter.

[0019] Figure 2 is the whole side view of said catheter.

[0020] Figure 3 is the cross sectional view of the boundary part between the base part and the end part.

[0021] Figure 4 and 5 show the other embodiment of the present invention.

[0022] Figure 4 is a perspective view to illustrate the manufacturing process of a catheter.

[0023] Figure 5 is the enlarged cross sectional view of the boundary part between the base part and the end part.

[0024] Figure 1 to Figure 3 relate to an embodiment of the present invention. A catheter (1) shown in Figures has a tube wall having a three-layer structure which consists of an inner layer (2), a middle layer (3) and an outer layer (4) and assuming the bending modulus of elasticity of said inner layer (2) at a temperature close to the bodily

temperature is G_1, the bending modulus of elasticity of said middle layer (3) at a temperature close to the bodily temperature is G_2, and the bending modulus of elasticity of said outer layer (4) at a temperature close to the bodily temperature is G_3, 15000 kgf/cm^2 $\geqq G_1 \geqq G_2 \geqq G_3 \geqq$ 1000 kgf/cm^2, preferably 15000 kgf/cm^2 $\geqq G_1 \geqq$ 8000 kgf/cm^2, 6000 kgf/cm^2 $\geqq G_2 \geqq$ 4000 kgf/cm^2, 3500kgf/cm^2 $\geqq G_3 \geqq$ 1000 kgf/cm^2 and the material of said inner layer (2) keeps the glassy state at the bodily temperature when said catheter (1) is inserted into the body and the material of said outer layer (4) is in the rubbery state at the bodily temperature when said catheter (1) is inserted into the body. Accordingly, the glass transition temperature Tg_1 of said inner layer (2) is set to be higher than the bodily temperature T_o ($Tg_1 > T_o$)and the glass transition temperature Tg_3 of said outer layer (4) is set to be equal to or lower than the bodily temperature T_o ($Tg_3 \leqq T_o$). Wherein T_o is, for example, in the range between 35 to 37°C but may reach 40°C when the body has hyperthermia.

[0025] Further, in the case where the material of each layer of said catheter (1) is an incomplete amorphous material, it is desirable that the crystallinity of said outer layer is equal to or lower than 30% at the bodily temperature T_o.

[0026] The material of said catheter is, for example, urethane elastomers, styrene elastomers, ester elastomers, olefin elastomers, amido elastomers, fluoroelastomers or mixtures of two or more kinds of these elastomers. A filler having radiopacity such as barium sulfate and the like is preferably added to said elastomers in an amount between 30 to 50% by weight so that a catheter can be detected by radiography.

[0027] As shown in Figure 2, said catheter (1) consists of a base part (IA) and an end part (1B), and generally it is preferable that said base part (1A) has high rigidity and said end part (1B) has flexibility.

[0028] To give said base part (1A) high regidity, and said end part (1B) flexibility, the thickness tA_1 of said inner layer (2) of said base part (1A) is set to be larger than the thickness tB_1 of said inner layer (2) of said end part (1B), and the thickness tA_3 of said outer layer (4) of said base part (1A) is set to be less than the thickness tB_3 of said inner layer (2) of said end part (1B). Concretely, in said base part (1A), 0.18 mm $\leqq tA_1 \leqq$ 0.19 mm, 0.03 mm $\leqq tA_3 \leqq$ 0.05 mm, $tA_1 > tA_3$, and in said end part (1B), 0.07 mm $\leqq tA_1 \leqq$ 0.09 mm, 0.14 mm $\leqq tA_3 \leqq$ 0.15 mm, $tA_1 < tA_3$ and $tA_1 > tB_1$, $tA_3 < tB_3$.

[0029] Total thickness of the tube wall of said catheter (1) is generally 0.6 to 0.7 mm so that the thickness tA_2 of said middle layer (3) of said base part (1A) is $t - tA_1 - tA_3$ and the thickness tB_2 of said middle layer (3) of said end part (1B) is $t - tB_1 - tB_3$ ($tA_2 = t - tA_1 - tA_3$, $tB_2 = t - tB_1 - tB_3$).

[0030] When said catheter (1) of this embodiment is inserted into the body and effected by the bodily temperature, the bending modulus of elasticity G_3 of said outer layer (4) is set to be low, such as 3500 kgf/cm^2 $\geqq G_3 \geqq$ 1000 kgf/cm^2, and said outer layer (4) is set to be in the rubbery state, so that said catheter (1) has enough flexibility to bend easily following the curve shape of the blood vessel and said outer layer (4) can follow a curve having a small curvature radius without cracking or breaking.

[0031] Further, in the case of the curve having a small curvature radius, if the crystallization of said outer layer (4) by tensile stress advances, said outer layer (4) may harden to be in danger of cracking or breaking while said outer layer (4) of said catheter (1) of this embodiment shows no advance of the crystallization by tensile stress.

[0032] Further, when the tube is molded by extrusion using a rigid material, sinks may be formed on the surface of the tube. However, in this embodiment, the inside layer of said rigid material is covered with the outside layer of a soft material having good fluidity filling up said sinks of the inside layer to obtain a catheter having a smooth surface without unevenness. If a catheter has an uneven surface, it is feared that the thrombus adheres to said catheter resulting in the difficulty of inserting said catheter into the blood vessel.

[0033] As above described, said outer layer of said catheter of this embodiment is so soft that safety in diagnosis or therapeutic is guaranteed without injuring the blood vessel and the like.

[0034] Further, as said inner layer (2) of said catheter (1) of this embodiment has a high bending modulus of elasticity G_1 such as 15000 kgf/cm^2 $\geqq G_1 \geqq$ 8000 kgf/cm^2 and the glass temperature of said inner layer (2) is set to be higher than the bodily temperature, said catheter (1) has an enough torque transmission property when said catheter (1) is inserted into the body and easy operation for diagnosis or therapeutic is guaranteed.

[0035] Still further, in said catheter (1) of this embodiment, as the bending modulus of elasticity becomes gradually higher from the inner layer to the outer layer, the difference of the mechanical property between a pair of layers attaching to each other may become small, resulting in high interlaminate strength and. folding by stress concentration is effectively avoided.

[0036] Figure 4 and Figure 5 show the other embodiment of the present invention.

[0037] As shown in Figure 4, the outside of a core bar (16) is covered with a melted material or a solution of a material by coating or extrusion to form an inner layer (12) by cooling or drying and then a tubular metal net is wound on said inner layer (12) in a base part (11A) as a metal reinforcement (15). The same material as used in the prior embodiment is used in this embodiment.

[0038] Said metal reinforcement (15) is covered with a middle layer (13) and further said middle layer (13) is covered with an outer layer (14). Said middle layer (13) and said outer layer (14) may be formed by coating or extrusion using the same material as used in the prior embodiment. Preferably, the same material is used for said middle layer (13) and said outer layer (14) to obtain

higher interlaminate strength.

[0039] As shown in Figure 5, a catheter (11) having three layer structure consisting of said inner layer (12), and middle layer (13) and said outer layer (14) is manufactured by the process as above described. Said base part (11A) has high rigidity by inserting said metal reinforcement (15) between said inner layer (12) and said middle layer (13) to obtain a good torque transmission property. Further, said catheter (11) has a smooth surface without unevenness since unevenness of the surface of said middle layer caused by unevenness of said metal reinforcement is filled by said outer layer (14), and said end part (11B) has enough flexibility since no metal reinforcement is inserted in the end part (11B).

[0040] The catheter of the present invention has a polylayer structure with more than three layers and in the case where the mechanical property changes gradually from inside layer to outside layer to obtain the minimum difference of the mechanical property between a pair of layers attaching to each other, high interlaminate strength is guaranteed and stress concentration is avoided. Further, in the case where the metal reinforcement is used to obtain high rigidity, a catheter having a smooth surface without unevenness is obtained when said metal reinforcement is inserted between a pair of layers.

Claims

1. A catheter whose tube wall has a polylayers structure with more than three layers.

2. A catheter of Claim 1, wherein said catheter consists of a base part and an end part, said base part is reinforced by a metal reinforcement arranged on the outside of the inner layer.

3. A catheter of Claim 1 or 2, wherein the glass transition temperature of said polylayer becomes gradually higher from the inside to the outside and the glass temperature of the outer layer is equal to or lower than the bodily temperature.

4. A catheter of Claim 2 or 3, wherein said catheter has a three layer structure consisting of an inner layer, a middle layer, and an outer layer and said metal reinforcement arranged on the outside of the inner layer is covered with said middle layer and said middle layer and outer layer are made of the same material.

5. A catheter of any of claims 1 to 4, wherein the material of said outer layer is in the rubbery state at the bodily temperature when said catheter is inserted into the body, the bending modulus of elasticity of said material is more than 1000 kgf/cm^2 at a temperature close to the bodily temperature, the material of said inner layer keeps the glassy state at the bodily temperature when said catheter is inserted into the body, and the bending modulus of elasticity of said material is more than 2500 kgf/cm^2 at 23°C.

6. A catheter of claim 4, wherein 15000 kgf/cm^2 $\geqq G_1 \geqq$ 8000 kgf/cm^2 and 3500 kgf/cm^2 $\geqq G_3 \geqq$ 1000 kgf/cm^2 wherein G_1 is the bending modulus of elasticity of said inner layer and G_3 is the bending modulus of elasticity of said outer layer.

7. A catheter of Claim 5 or 6, wherein said catheter consists of a base part and an end part, the thickness of the inner layer of said base part is larger than the thickness of the inner layer of said end part.

Fig. 1

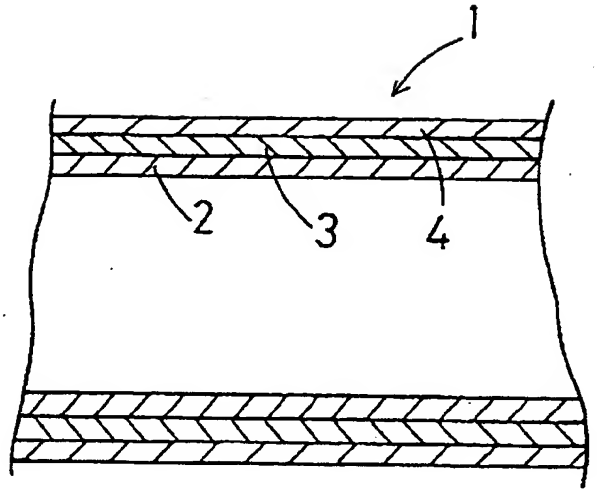
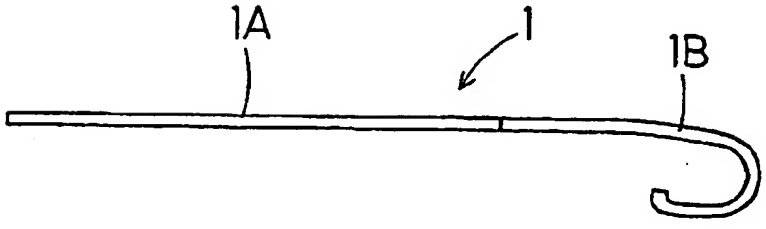


Fig. 2



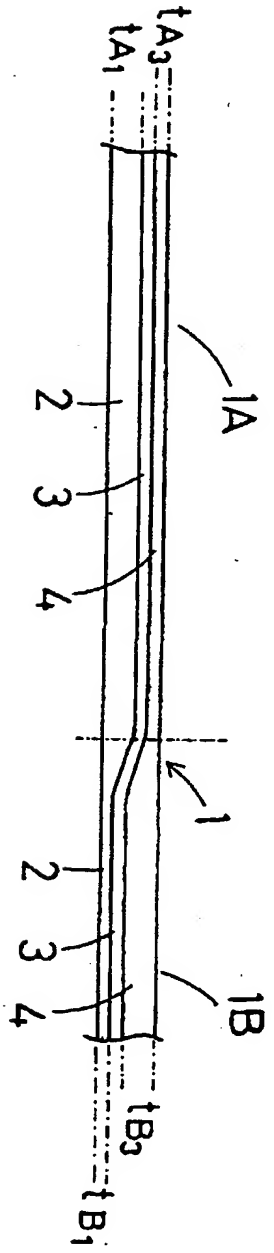


Fig. 3

Fig. 4

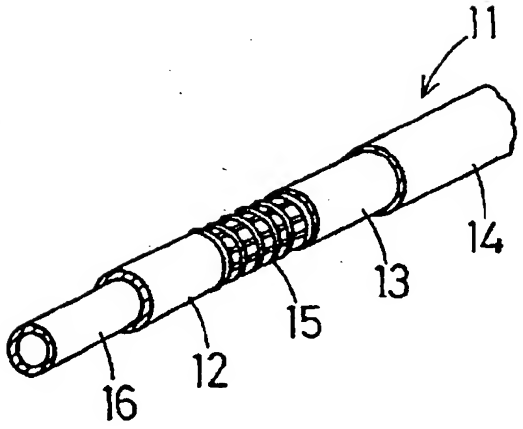
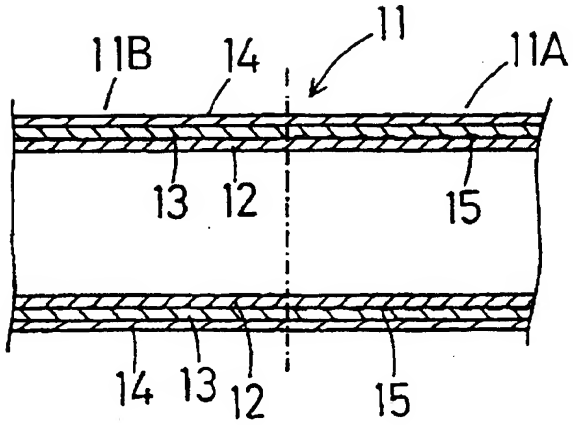


Fig. 5



(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 931 558 A3

(12) **EUROPEAN PATENT APPLICATION**

(88) Date of publication A3:
05.01.2000 Bulletin 2000/01

(43) Date of publication A2:
28.07.1999 Bulletin 1999/30

(21) Application number: **99101045.5**

(22) Date of filing: **22.01.1999**

(51) Int Cl.[7]: **A61M 25/00**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **23.01.1998 JP 2662198**

(71) Applicant: **Asahi Intecc Co., Ltd.**
Seto-shi, Aichi-ken (JP)

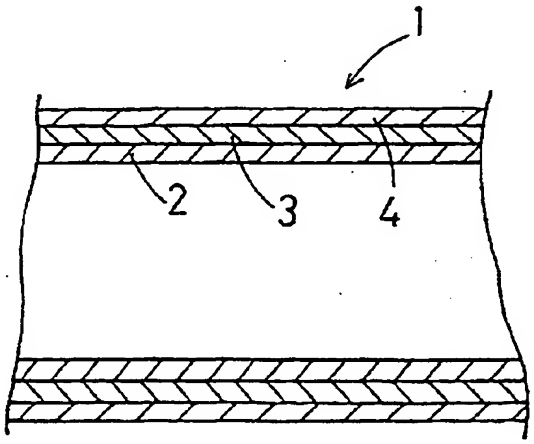
(72) Inventors:
- **Miyata, Masahiko**
  Seto-chi, Aichi (JP)
- **Kato, Tomihisa**
  Seto-shi, Aichi (JP)

(74) Representative: **VOSSIUS & PARTNER**
Siebertstrasse 4
81675 München (DE)

(54) **A catheter**

(57) The object of the present invention is to present a catheter which can be safely inserted into the body and easily operated in said body. To attain this object, a catherter whose wall has a polylayer structure with more than three layers is provided in the present invention. In said catheter, the mechanical property changes gradually from inside layer to outside layer to obtain the minimum difference of the mechanical property between a pair of layers attaching to each other, so that high interlaminate strength is guaranteed and stress concentration is avoided. Further, in the case where the metal reinforcement is wound on the inner layer to obtain high rigidity, a catheter has a smooth surface without unevenness.

Fig. 1



EP 0 931 558 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 99 10 1045

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO 96 33763 A (TARGET THERAPEUTICS) 31 October 1996 (1996-10-31) * page 17, line 6 - page 19, line 6 * * page 24, line 29 - page 26, line 4 * * figures 8-10 *	1,2,4	A61M25/00
A		7	
A	EP 0 102 685 A (MALLINCKRODT, INC) 14 March 1984 (1984-03-14) * page 5, line 2 - line 28 *	3,5,6	
A	EP 0 420 993 A (MITSUBISHI) 10 April 1991 (1991-04-10) * page 4, line 6 - line 50 * * page 5, line 23 - line 58 *	3	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61M A61L

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 November 1999	Schönleben, J

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 99 10 1045

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-11-1999

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9633763 A	31-10-1996	US 5702373 A	30-12-1997
		AU 693357 B	25-06-1998
		AU 5578596 A	18-11-1996
		AU 6803098 A	01-10-1998
		CA 2182526 A	29-10-1996
		EP 0782463 A	09-07-1997
		JP 2865428 B	08-03-1999
		JP 9506541 T	30-06-1997
		NO 963273 A	31-10-1996
		US 5891112 A	06-04-1999
EP 102685 A	14-03-1984	US 4464176 A	07-08-1984
		CA 1195576 A	22-10-1985
		DE 3378189 A	17-11-1988
		ES 522968 A	01-11-1984
		ES 533913 A	01-11-1985
		JP 1842111 C	12-05-1994
		JP 4009547 B	20-02-1992
		JP 58218966 A	20-12-1983
		ZA 8303673 A	29-08-1984
EP 420993 A	10-04-1991	DE 69016905 D	23-03-1995
		DE 69016905 T	08-06-1995
		US 5441489 A	15-08-1995
		CA 2030786 A,C	14-10-1990
		WO 9011793 A	18-10-1990
		JP 2523405 B	07-08-1996

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82